JUL 22 2004

K040923

SUMMARY OF

SAFETY AND EFFECTIVENESS
FOR IBL PROGESTERONE LIA

Manufacturer: IBL Immuno Biological Laboratories
Flughafenstrasse 52A, D-22335
Hamburg Germany

Contact Information: Lehnus & Associates
Gary Lehnus
150 Cherry Lane Rd.
East Stroudsburg, PA 18301
Tel: (570) 620-0198

Device Name / Classification:
The device trade name is the IBL Progesterone LIA having FDA assigned name: Progesterone test system, 21 CFR, **862.1620**, categorized as Class I "exempt" medical devices for the Clinical Chemistry and Clinical Toxicology Panel, as Product Code **JLS.**

Device Description:
Luminescence immunoassay (LIA) based on the competition principle. An unknown amount of antigen present in the sample and a fixed amount of enzyme labeled antigen compete for the binding sites of the antibodies coated onto the wells. After incubation the wells are washed to stop the competition reaction. After addition of the luminescence substrate solution the intensity of the luminescence measured is inversely proportional to the amount of the antigen in the sample. Results of samples can be determined directly using the standard curve.

Device Intended Use:
Luminescence immunoassay for the *in vitro diagnostic* quantitative measurement of active free progesterone (a female hormone) in saliva. Measurements obtained by this device may be used in the diagnosis and treatment of disorders of the ovaries and can be used as an aid for confirmation of ovulation.

Device Performance:

Studies were performed to establish levels of progesterone throughout the menstrual cycles of pre-menopausal women. Saliva samples were collected from apparently healthy females known to be pre-menopausal and using no contraceptives. Three saliva samples were collected per day and pooled and frozen prior to running the Progesterone LIA assay. Collection began at the last day of bleeding and continued daily until first day of bleeding. A total of 27 premenopausal women, six postmenopausal women and 49 males were evaluated for the studies.

Comparison studies were performed using saliva samples from 97 adult healthy populations. These samples were tested with the IBL Progesterone LIA and compared to a published procedure that used a modification in the handling of saliva for a typical RIA test. Results from measuring the saliva samples in both methods yielded a correlation of $r^2 = 0.94$ with a regression formula of Y=0.89*RIA + 25.5 pg/mL.

The overall performance of the IBL Progesterone LIA is shown below:

Analytical Specificity (Cross Reactivity)	Substance	% Cross-reactivity		Cross-reactivity of other substances tested ≤ 0.1 %
	17α-Hydroxyprogesteron	1.84		
	6α-Methyl-17α-Hydroxyprogesteron	1.41		
	Pregnenolone	0.41		
	Deoxycorticosterone	0.28		
	Androsterone Sulfat	0.25		
	Androstenedion	0.20		
	Androsterone	0.20		
	DHEA-S	0.11		
	Corticosterone	0.06		
Analytical Sensitivity (Limit of Detection)	2.6 pg/mL	Mean signal (Zero-Standard) - 2SD		
Precision	Range (pg/mL)	CV (%)		
Intra-Assay (10)	11.5 - 822	6.0 – 0.7		
Inter-Assay (10)	10.6 – 817.1	18.8 – 3.4		
Linearity	Range (pg/mL)	Range (%)	Mean (%)	Serial dilution up to 1 : 32
	7.5 - 779	78 - 120	97	
Recovery	Range (pg/mL)	Range (%)	Mean (%)	
	27 - 1497	82 - 121	103	

Normal ranges	**Progesterone (pg/mL)**		
♀	Premenopausal (n = 27 month profiles)	Follicular phase	28 -82 pg/mL
		Luteal phase (peak max)	127 - 446 pg/mL
	Postmenopausal, n = 6	-	18 - 51 pg/mL
♂	n = 49	-	< 59 pg/mL

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 22 2004

IBL-Hamburg
c/o Mr. Gary Lehnus
Lehnus & Associates Consulting
150 Cherry Lane Rd.
East Stroudsburg, PA 18301

Re: k040923
Trade/Device Name: IBL Progesterone LIA Test
Regulation Number: 21 CFR 862.1620
Regulation Name: Progesterone test system
Regulatory Class: Class I
Product Code: JLS
Dated: June 10 2004
Received: June 17, 2004

Dear Mr. Lehnus:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040923

Device Name: IBL Progesterone LIA Test

Indications For Use:

Luminescence immunoassay for the *in vitro diagnostic* quantitative measurement of active free progesterone (a female hormone) in saliva. Measurements obtained by this device may be used in the diagnosis and treatment of disorders of the ovaries and can be used as an aid for confirmation of ovulation.

The IBL SaliCap Set is used for the collection, handling, and storage of saliva used in the Progesterone LIA assay.

Prescription Use X **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040923